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FILING DATE APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 1.1 4

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EXAMINER

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ART UNIT 36

PAPER NUMBER

THE STATE OF THE S NEW ATTR MA 1.082

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

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Commissioner of Patents and Trademarks

Office Action Summary		Application No.	Applicant(s)	
		09/046,833	LIU ET AL.	
		Examiner	Art Unit	
		David Guzo	1636	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status				
1)⊠	Responsive to communication(s) filed on 30 f	November 2000 .		
2a) <u></u> □	This action is FINAL . 2b)⊠ Th	is action is non-final.		
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims				
4)⊠ Claim(s) 68-74 is/are pending in the application.				
4a) Of the above claim(s) is/are withdrawn from consideration.				
5) 🗌	5) Claim(s) is/are allowed.			
6)⊠	6)⊠ Claim(s) <u>68-74</u> is/are rejected.			
7) 🗌	Claim(s) is/are objected to.			
8) Claims are subject to restriction and/or election requirement.				
Application Papers				
9) The specification is objected to by the Examiner.				
10) The drawing(s) filed on is/are objected to by the Examiner.				
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.				
12) The oath or declaration is objected to by the Examiner.				
Priority under 35 U.S.C. § 119				
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).				
a) ☐ All b) ☐ Some * c) ☐ None of:				
 Certified copies of the priority documents have been received. 				
2. Certified copies of the priority documents have been received in Application No				
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).				
14) Acknowledgement is made of a claim for democrac priority and of the control of the control of the claim for democracy priority and of the control of the				
Attachment(s)				
15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s) 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20) Other:				

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DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Salmons et al. or Smith et al.

This rejection is maintained for reasons of record in the previous Office Action (Paper #7) and for reasons outlined below.

Applicants have amended claim 68 to insert the word "localized" prior to "complex".

Applicants assert that neither Salmons et al. nor Smith et al. teach the claimed localized specific complex.

Applicant's arguments filed 11/30/00 have been fully considered but they are not persuasive. The recited limitation of a specific "localized" complex does not distinguish the claims over Salmons et al. or Smith et al. As previously noted by the examiner, the Salmons et al. and Smith et al. references both recite packaging cell lines which comprise a viral (retroviral) vector comprising a nucleic acid component and a non-nucleic acid component (i.e. gag, pol or env proteins) being capable of forming a specific complex with each other in the context of a viral vector particle. The aforementioned complexes must be "localized" to the extent that they are localized to parts of the cell where the viral particles are formed by the specific complexing of vector nucleic acids and proteins such as gag or pol, etc. The complexes are also localized in

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that the non-nucleic acid components are specifically localized and complexed with the nucleic acid component of the vector in the context of formation of the viral vector particle.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 69 and 71-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 69 is vague in the recitation of the phrase "...cell line is native to said viral vector." It is unclear if by "native" to the viral vector applicants are indicating that the cell line is naturally capable of being infected by the virus or is capable of being infected by the virus and is capable of supporting replication of the virus, etc.

Claims 71-73 are vague for reasons of record in the previous Office Action and for reasons outlined below.

Applicants have traversed this rejection by asserting that the skilled artisan would appreciate the metes and bounds of the claimed invention.

In response, the examiner notes that the claim language is unclear. If for example, a promoter of the recited vector is from a retrovirus genome and a termination sequence is from an AAV genome, is a coding sequence from the same AAV genome a non-native sequence to the vector or is it native to the vector because it is also from the AAV genome which is part of the vector?

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard A. Schwartz, can be reached on (703) 308-1133. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo December 14, 2000

> DAVID GUZO PRIMARY EXAMINER